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Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority Pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five jears. These addenda represent an updated literature search current as of 1988, plus additional information form Agency files and Program Offices. This addendum is to update the existing Ambient Water Quality Criteria Document for Acrolein.

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ADDENDUM FOR ACROLEIN

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AND STANDARDS

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PREFACE

Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information from Agency files and Program Offices. The first draft of this addendum was prepared by Syracuse Research Corporation under contract no. 68-C8-0004.

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LIST OF ABBREVIATIONS

ADI	Acceptable daily intake
BCF	Bioconcentration factor
CRAVE	Carcinogen Risk Assessment Verification Endeavor
PEL	Permissible exposure level
RFD	Reference dose
STEL	Short-term exposure level
TLV	Threshold limit value
TWA	Time-weighted average

INTRODUCTION

Under Section 304(a)(1) of the Clean Water Act of 1977 as amended in 1987, the U.S. EPA is required to publish criteria for water quality accurately reflecting the latest scientific knowledge regarding the effects on health and welfare that may occur from the presence of pollutants in any body of water, including groundwater. In accordance with the 1977 act, Ambient Water Quality Criteria Documents (AWQCDs) were developed in 1980 for 65 toxic pollutants or classes of pollutants listed under Section 307(a)(1).

These addenda are intended to serve as an update of the original AWQCDs. The addenda provide the Agency with the latest scientific assessments of potential health hazards associated with these pollutants and serve as guidelines for modifying the current (1980) AWQCDs.

The human health criteria in these addenda are based on Agency verified risk assessment values when available. These values consist of reference doses (RfD) for those chemicals believed to be systemic toxicants (i.e., do not induce cancer) and cancer risk factors for those thought likely to cause cancer in humans. The verification process consists of a review and consensus of risk assessment values provided by an Agency workgroup consisting of scientists from each of the major Agency offices. Assessments for noncarcinogens are verified by the RfD workgroup and those for carcinogens are verified by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) workgroup. If such values are not available, the criteria are based on the most recent Agency health assessment. In the absence of any appropriate Agency value, RfD values or cancer risk factors are derived by current Agency methods if adequate new data are available, and criteria are recommended based on the proposed RfD or risk factor.

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is derived by dividing a NOAEL or LOAEL for subchronic or chronic exposure by standard uncertainty factor(s) times an additional uncertainty factor:

$$RfD = \frac{\text{NOAEL or LOAEL}}{UF(s) \times UF}$$

The standard uncertainty factors are applied to reflect the various types of data used to estimate RfDs. An uncertainty factor of 10 is used to account for variations in human sensitivity when extrapolating from valid human studies involving long-term exposure of average, healthy subjects. An additional 10-fold factor is used for each of the following: to extrapolate from long-term animal studies to the case of humans, to extrapolate from subchronic animal studies to chronic exposure, and to extrapolate from a LOAEL to a NOAEL. An additional uncertainty factor of >0-10 may be applied to reflect professional assessment of the uncertainties of the study and data base not explicitly addressed by the standard uncertainty factors (i.e., completeness of the overall data base). The default value for the additional uncertainty factor is 1.

In assessing the carcinogenic potential of a chemical, the U.S. EPA classifies the chemical into one of the following groups according to the degree of evidence in epidemiological studies and animal studies: Group A - Human Carcinogen; Group B - Probable Human Carcinogen [limited evidence in humans with or without sufficient evidence in animals (Group B1) or inadequate evidence in humans with sufficient evidence in animals (Group B2)]; Group C - Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); Group D - Not Classifiable as to

Human Carcinogenicity (inadequate or no evidence); Group E - Evidence of Noncarcinogenicity for Humans. Quantitative carcinogenic risk assessments are performed for chemicals in Groups A and B, and on a case-by-case basis for chemicals in Group C. Upper-bound cancer unit risks (slope values) are estimated through the use of mathematical extrapolation models. Most commonly for animal data, the linearized multistage model with a 95% upper confidence limit is used to provide a low-dose estimate of cancer risk. The cancer risk is characterized as an upper-limit estimate (i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-limit estimate and in fact may be lower). Alternative risk models to the multistage model, such as the one-hit, Weibull, Logit or Probit model, are available and may be used when the evidence indicates that they may be more appropriate. In the absence of such evidence, the Agency recommends the linearized multistage model to provide consistency of approach and an upper-bound on the potential carcinogenic risk. In the case where human data are used for quantitative risk assessment, an upper-bound estimate rather than a 95% upper-bound estimate is used when low-dose linearity is assumed.

In the development of this Addendum to the AWQCD on acrolein, recent Agency assessments have been consulted. A computerized literature search was conducted to cover studies published more recently than the latest Agency assessment (i.e., published in 1987 to 1988). New key studies have been evaluated.

REVIEW OF NEW DATA

Toxicologic/Carcinogenic Effects

The latest Agency document (U.S. EPA, 1987) describes an oral carcinogenicity study, which has recently been published (Lijinsky and Reuber, 1987).

Lijinsky and Reuber (1987) administered acrolein in drinking water to groups of 20 male and/or 20 female F344 rats. The male rats were given concentrations of 0, 100, 250 or 625 mg/ℓ, 5 days/week for 104-124 weeks and the females received only the highest dose of 625 mg/ℓ. Each cage (4 rats/cage) received 80 mℓ/day of water containing the various concentrations of acrolein for 5 days and an unlimited supply of tap water on the remaining 2 days of the week. The authors calculated the total doses of acrolein to be 0, 1.2 (in 124 weeks), 3.1 (in 124 weeks) and 6.5 g (in 104 weeks). The median time of death was 115-129 weeks for all groups, and treatment did not affect mortality. The surviving rats were killed at 123-132 weeks, and the major organs and tissues (not specified) were examined histologically. Complete details of tumor incidence were not provided. Tumors were observed in several organs in both treated and untreated males, but the lack of statistical significance or a dose response indicates that none of the tumors in the males were due to the treatment.

In the female rats, adrenal cortical tumors were seen in 5/20 treated rats, and in only 1/20 control rats ($p=0.091$, Fisher exact test, 1 tailed). The combined incidence of adrenal cortical adenomas and hyperplastic nodules of the adrenal cortex was elevated in treated as compared with control females ($p=0.022$; incidences were not reported clearly).

In males, the incidence of atrial and hepatic vein thrombosis was increased slightly at the low doses, but the statistical significance was not reported and no increase was seen at the highest dose. Incidences were not clearly reported for all groups. The authors reported that no other histopathological changes were seen.

In an inhalation study, male Sprague-Dawley rats (40/group) were exposed to 0, 0.17, 1.07 or 2.98 ppm of acrolein 6 hours/day, 5 days/week for 3 weeks (Leach et al., 1987). No changes were found in lung histology or immune function. At the highest concentration (2.98 ppm), body weights and absolute spleen weights were depressed. The nasal turbinates showed metaplastic, hyperplastic and dysplastic changes in the mucus, respiratory and olfactory epithelium.

Acrolein is classified in U.S. EPA Group C - a possible human carcinogen. This classification is based on a limited evidence of increased incidence of adrenal cortical adenomas in female rats (Lijinsky and Reuber, 1987) and no evidence of carcinogenicity in humans. It is supported by several studies demonstrating a carcinogenic potential for glycidaldehyde, a known metabolite of acrolein (U.S. EPA, 1989). It is further supported by evidence that acrolein is mutagenic in bacteria and is structurally related to probable or known human carcinogens (e.g., formaldehyde and vinyl chloride) (U.S. EPA, 1989). Detailed descriptions of these studies are available in U.S. EPA (1987).

Bioconcentration Factor (BCF)

Pertinent new information concerning the bioconcentration factor for acrolein is currently undergoing Agency review. The BCF value of 215 determined in U.S. EPA (1980) will be used until this review has been completed.

QUANTIFICATION OF EFFECTS

The 1980 AWQCD (U.S. EPA, 1980) based the criteria on an ADI of 0.016 mg/kg/day, which was derived from a study by Newell (1958). Rats were provided with drinking water containing concentrations of 5, 13, 32, 80 and 200 mg/ℓ for 90 days. No effects were observed on hematological parameters, organ weights or pathology. The only adverse effect was decreased water intake for the first 3 weeks. The dosage of 15.6 mg/kg/day was calculated from 200 mg/ℓ, assuming that a 450 g rat drinks 35 mℓ in a day. Applying uncertainty factors of 10 each for use of a subchronic study, interspecies extrapolation and protection for the most sensitive human results in a value of 0.0156 mg/kg or 1.09 mg/day for a 70 kg human.

In the absence of adequate new oral data, no new criteria are recommended. Retaining the derivation in U.S. EPA (1980), the criterion is calculated as 1.09 mg/day/[2 ℓ/day + (0.0065 kg/day x BCF)], where the BCF = 215. The criterion is therefore 0.32 mg/ℓ or 320 µg/ℓ for consumption of water and fish and shellfish. For consumption of fish only, the criterion would be 1.09/(0.0065x215) = 0.78 mg/ℓ or 780 µg/ℓ.

The study by Lijinsky and Reuber (1987) is the primary basis for the classification of acrolein in U.S. EPA Group C - a possible human carcinogen. However, a cancer potency value for acrolein is not available as yet since the Agency's most recent assessment predates this bioassay.

EXISTING STANDARDS AND CRITERIA

The ACGIH (1987) TLV-TWA for acrolein is 0.1 ppm (~0.25 mg/m^3); the TLV-STEL is 0.3 ppm (~0.8 mg/m^3). The OSHA (1985) PEL is 0.1 ppm.

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